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January 20, 2005 (Date) Paula S. Hartchart (Signature)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Preston H. Dorsett
Frances I. Byrd
Robert F. Devlin

Serial No.: 10/696,635

Filed: October 29, 2003

For: IMPROVED SPECIFICITY IN THE DETECTION OF ANTI-RUBELLA IGM ANTIBODIES

Confirmation No.: 5529

Group Art Unit: 1648

Examiner: LUCAS, ZACHARIAH

Atty. Dkt. No.: 13096.0020.DVUS02

COMMENTS ON REASONS FOR ALLOWANCE ENCLOSED WITH

NOTICE OF ALLOWANCE **DATED NOVEMBER 3, 2004**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is submitted as comment on the "Reasons for Allowance" given by the Examiner as part of the Notice of Allowance mailed November 3, 2004. It is submitted concurrently with the payment of the issue and is therefore timely filed.

It is believed that no fee is due; however, should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Deposit Account No. 01-2508/**13096.0020.DVUS02**.

COMMENTS

At page two of the "Detailed Action" the Examiner remarks *inter alia* that:

> [t]he second vessel is described as 'containing an indicator reagent that specifically complexes with an anti-rubella IgM antibody.' This limitation is read as requiring that the claimed indicator reagent is capable of distinguishing IgM antibodies that bind to the rubella E1 and E2 antibodies from other antibody types that may be found in the sample to be tested (*e.g.* will not recognize anti-rubella IgG antibodies).

Applicant wishes to make clear that the indicator reagent, by itself, will recognize any IgM antibody, whether the IgM is specific for rubella or not (the indicator is IgM specific). This is the reason previous tests were plagued by false positives. In previously know methods the IgM present might bind non-specifically (*e.g.* to a capsid protein) and then be detected by the conjugate.

One remarkable feature of the present invention is that the rubella antigen used is bound to anti-rubella antibodies (either IgM or IgG antibodies) with much higher fidelity. Thus, there is far less cross-reactivity of non-rubella antigens and, therefore, few, if any, false positive results. In sum, the indicator is specific in that it recognizes IgM antibodies and does not recognize other antibody types (*e.g.* IgG). Among the IgM antibodies specifically recognized are those that bind the rubella antigens with high fidelity. The genius of the invention is that the antigen binds the anti-rubella IgM antibodies with much higher fidelity. This results in fewer false positives because the diagnostic kit functions by measuring the level of antibody bound to antigen.

Applicant further wishes to make it clear the antigen of the instant invention will bind to both anti-rubella IgG and IgM antibodies. However, the great advantage recognized by the inventors is that the antigen binds to IgM with greater fidelity than antigens previously used to detect anti-rubella IgM antibodies. That is, as compared with what was previously available, antigens used for the currently claimed diagnostic kits exhibit far less non-specific anti-rubella IgM recognition, resulting in few, if any, positive results.

The Examiner is invited to contact the undersigned attorney at 713.787.1589 with any questions, comments, or suggestions relating to the referenced patent application.

Respectfully submitted,

Matthew L. Madsen
Reg. No. 45,594
Attorney for Assignee
VIRAL ANTIGENS, INC.

HOWREY SIMON ARNOLD & WHITE, LLP
2941 Fairview Park Drive, Box 7
Falls Church, VA 22042
703.336.6950
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